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FILING DATE

FIRST NAMED APPLICANT ATTY, DOCKET NO.

01/30/98 MURPHY G 8511-007

020583 HM12/0621 PENNIE AND EDMONDS 1155 AVENUE OF THE AMERICAS

NEW YORK NY 10036-2711

DATE MAILED: 06/21/00

EXAMINER

PAPER NUMBER

V

This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS

## **OFFICE ACTION SUMMARY**

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Responsive to communicati	on(s) filed on 4 - 5 - 5-	O
This action is FINAL.		
	condition for allowance except for form e under <i>Ex parte Quayle</i> , 1935 D.C. 1	nal matters, <b>prosecution as to the merits is closed</b> in 11; 453 O.G. 213.
whichever is longer, from the ma		month(s), or thirty days, lure to respond within the period for response will cause s of time may be obtained under the provisions of 37 CFR
Disposition of Claims		
Claim(s)	>	is/are pending in the application. is/are withdrawn from consideration. is/are allowed. is/are rejected. is/are objected to. are subject to restriction or election requirement.
Of the above, claim(s)	- 22, 25- 27	is/are withdrawn from consideration.
Claim(s)	- 20 2	is/are allowed.
	, 26, 28-30	is/are rejected.
Claim(s)		Is/are objected to.
		are subject to restriction of election requirement.
Application Papers		•
See the attached Notice of I	Draftsperson's Patent Drawing Review	w. PTO-948.
		is/are objected to by the Examiner.
		is approved disapproved.
The specification is objected	d to by the Examiner.	
The oath or declaration is of	bjected to by the Examiner.	•
Priority under 35 U.S.C. § 119		
Acknowledgment is made o	of a claim for foreign priority under 35	U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ Nor	ne of the CERTIFIED copies of the	priority documents have been
received.		
	No. (Series Code/Serial Number)	· · · · · · · · · · · · · · · · · · ·
received in this national	d stage application from the Internation	nal Bureau (PCT Rule 17.2(a)).
*Certified copies not received	l:	
Acknowledgment is made o	of a claim for domestic priority under 3	5 U.S.C. § 119(e).
Attachment(s)		
Notice of Reference Cited, I	PTO-892	
Information Disclosure Statement(s), PTO-1449, Paper No(s).		
Interview Summary, PTO-413		
Notice of Draftperson's Patent Drawing Review, PTO-948		
Notice of Informal Patent Application, PTO-152		
		THE FOLLOWING PAGES
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Effective February 7, 1998, the Group Art Unit location has been changed, and the examiner of the application has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Minh-Tam Davis, Group Art Unit 1642.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 23-24, 26, and 28-30 are being examined.

The following are the remaining rejections.

## **REJECTION UNDER 35 USC 102**

Rejection under 35 USC 102(e) of claims 23 and 24 pertaining to anticipation by Cohen et al remains for reasons already of record in paper No. 9.

Appliant argues as follows:

The dendritic cells taught by Cohen et al is different from the claimed composition because of the following reasons: Based on the upregulation of phenotypic markers CD14, B7.1 and B7.2, which only are useful for demonstrating that monocytes are differentiated to a dendritic cells, one could not anticipate nor expect that the dendritic cells produced by the methods of Cohen et al would be functional, and could process and present antigen.

Applicant's arguments set forth in paper No.10 have been considered but are not deemed to be persuasive for the following reasons:

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One of ordinary skill in the art would have expected that the dendritic cells produced by the methods of Cohen et al are fully functional, and could process and present antigen for the following reasons: 1) The dendritic cells produced by the methods of Cohen et al are fully functional because injection of said cells, which are previously exposed to a prostate tumor lysate, could reduce the size of the protate tumor in a cancer patient, and 2) It is well known in the art that dendritic cells are antigen presenting cells, therefore, functional dendritic cells would inherently process and present antigens, after exposure to said antigens.

## **REJECTION UNDER 35 USC 103**

1. Rejection under 35 USC 103 of claim 26 pertaining to obviousness by Cohen et al in view of Lutz et al, remains for reasons already of record in paper No. 9.

Appliant argues as follows:

Lutz et al add nothing to make it obvious to provide dendritic cells, which have extended life span or or immortalized, and which could process antigens. Furthermore, unlike immortalized cells, the claimed dendritic cells with extended life span are limited in the number of replicative cycles they may undergo.

Applicant's arguments set forth in paper No.10 have been considered but are not deemed to be persuasive for the following reasons:

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Claim 26 does not recite any limitation concerning the number of replicative cycles that the claimed dendritic cells may undergo. In addition, even if claim 26 recites said limitation, claim 26 is still obvious, because immortalized cells would have extended life span, and functionally are not any different from the claimed dendritic cells.

2. Rejection under 35 USC 103 of claims 28 and 29, pertaining to obviousness by Cohen et al in view of Taylor et al, remains for reasons already of record in paper No. 9.

Applicant argues as follows:

There is no motivation to combine the references. Furthermore, there is no teaching in the references that cryopreserved dendritic cells remain capable of demonstrating the dendritic cell phenotype, much less remain capable of processing and presenting prostate antigen.

Applicant's arguments set forth in paper No.10 have been considered but are not deemed to be persuasive for the following reasons:

The motivation to use the cryopreservation techniques taught by Taylor et al to cryopreserve dendritic cells taught by Cohen et al is clear, i.e. by logical reasoning, it would have been obvious to cryopreserve dendritic cells so that one could use dendritic cells any time in the future, without having to maintain a culture of dendritic cells. See <u>In re Kerkhoven</u> (205 USPQ 1069, CCPA 1980), which summarizes:

"It is <u>prima facie</u> obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose: idea of combining them flows logically from their having been individually

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taught in prior art." Furthermore, one of ordinary skill in the art would have expected that the dendritic cells would remain as functional dendritic cells after cryopreservation, because cryopreservation is routine in the art to preserve cell function.

3. Rejection under 35 USC 103 of claim 30, pertaining to obviousness by Cohen et al in view of Taylor et al, further in view of Lutz et al, remains for reasons already of record in paper No. 9.

Applicant argues as follows:

As the dendritic cell composition is non-obvious, Lutz et al adds nothing to make it obvious to immortalize dendritic cells that have been previously cryopreserved. Furthermore, there is no motivation to combine the references.

Applicant's arguments set forth in paper No.10 have been considered but are not deemed to be persuasive for the following reasons:

The motivation to use the immortalization techniques taught by Lutz et al to immortalize dendritic cells taught by Cohen et al, which has been cryopreseved by the techniques of Taylor is as follows: By logical reasoning, it would have been obvious to cryopreserve dendritic cells so that one could use dendritic cells any time in the future, without having to maintain a fresh culture of dendritic cells, *supra*. Furthermore, immortalization of dendritic cell also overcomes the problem of not be able to maintain dendritic cells *in vitro* for a long period of time, as taught by Lutz et al. See <u>In re Kerkhoven</u> (205 USPQ 1069, CCPA 1980), which summarizes:

"It is <u>prima facie</u> obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very

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same purpose: idea of combining them flows logically from their having been individually taught in prior art."

All other rejections in the previous Office actions are withdrawn. NO CLAIMS ARE ALLOWED.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Tam B. Davis whose telephone number is (703) 305-2008. The examiner can normally be reached on Monday-Friday from 9:30am to 3:30pm, except on Wesnesday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4227.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0916.

Minh-Tam B. Davis

June 13, 2000